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EXAMINER				
KIM, TAEYOUN				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary

Application No.

10/646,615

Examiner

Taeyoon Kim

Applicant(s)

HENNEN, WILLIAM J.

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2008.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-8,11,12,14-16,18,50,53-57 and 59-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-8,11,12,14-16,18,50,53-57 and 59-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/9/2008 has been entered.

Applicant's amendment and response filed on 12/9/2008 has been received and entered into the case.

Claims 2, 3, 9, 10, 13, 17, 19-49, 51, 52 and 58 are canceled, claims 79 and 80 are newly added, and claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57 and 59-80 are pending and have been considered on the merits. All arguments have been fully considered.

The claim objection has been withdrawn due to the amendment.

The claim rejection under 35 U.S.C. §112 has been withdrawn due to the amendment.

Claim Objections

Claims 18, 59, 60, 62, 66, 67, 79 and 80 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The independent claims 1 and 50 have a transitional phrase "consisting of", and

therefore, the claims are closed excluding any ingredient other than the listed in the claims. However, the dependent claims 18, 59, 60, 62, 66 and 67 disclose further components to the independent claims, and therefore, the claims are not further limiting the parent claims.

Claims 79 and 80 disclose the term "red rice yeast extract". It appears that the term is supposed to be "red yeast rice extract" as known in the art. Appropriate correction is required. Accordingly, it is more appropriate as "red yeast rice extract" in the exemplary composition shown in the specification (p.9).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57 and 59-80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly introduced limitation of "vitamin-like substance" or "herb or plant extract" in the claims does not have a proper written descriptive support from the specification and thus, the limitation introduces a new matter to the current application.

New matter includes not only the addition of wholly unsupported subject matter,

but may also include adding specific percentages or compounds after a broader original disclosure, or even the omission of a step from a method. See MPEP § 608.04 to § 608.04(c). See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976) and MPEP § 2163.05 for guidance in determining whether the addition of specific percentages or compounds after a broader original disclosure constitutes new matter.

There is no disclosure to the limitation of "vitamin-like substance". While there are a few examples for the limitation of "herb or plant extract" in the specification, there is no proper description to encompass the entire scope of the "herb or plant extract" as in the claims, and thus, these limitations introduce a new matter.

Similarly, the limitation of "a carrier" in claims 79 and 80 introduces a new matter to the application. There is no adequate support for the limitation in the specification.

Claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57 and 59-78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current claims disclose the limitation of "low density lipoprotein (LDL) receptor-binding component" in claims 1, 59 and 74, "blood cholesterol reduction component or blood cholesterol reducing element" in claim 1, 66 and 74, "blood flow-enhancing component" in claims 1, 50 and 74, or "a fat oxidation prevention element" in

claims 18 and 67.

The current application generically claims any LDL receptor-binding component, any blood cholesterol reduction component, any blood flow-enhancing component or any fat oxidation prevention element, however the specification does not contain an adequate description for the entire scope of this limitation and thus the claims. The claims are not limited to a particular species just generically any of these component which is known in the art and those which have not been isolated and/or identified including variants of known elements. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

The claims are essentially of limitless breadth. It is implied that so long as the specification provides one with the ability to test any particular embodiment which is encompassed by the material limitations of a claim, one can thereby distinguish between those embodiments which meet the functional limitations from those embodiments which don't. This argument is not entirely without merit. However, the issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the

guidance presented in the instant specification and the prior art of record. This 'make and test' position is inconsistent with the decisions in *In re Fisher*, 427 F.2d 833, 166

Every species in a genus need not be described in order that a genus meets the written description requirement. See *Utter*, 845 F.2d at 998- 99, 6 USPQ2d at 1714 ("A specification may, within the meaning of §112, first paragraph, contain a written description of a broadly claimed invention without describing all species that claim encompasses.") In claims to a species from a genus, however, a generic statement without more, is not an adequate written description of the genus because it does not distinguish the claimed species of the genus from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, does not suffice to define the genus because it is only an indication of what the genus does, rather than what it is. See *Fiers*, 984 F.2d at 1169-71, 25 USPQ2d at 1605- 06 (discussing *Amgen*). It is only a definition of a useful result rather than a definition of what achieves that result. Many such species of the genus may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally thought to exist, in the absence of knowledge as to what that material consists of, is not a description of that entire material.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 7, 8, 11, 12, 14-16, 18, 50, 56, 57, 59-67 and 72-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Vester (US 6,203,818) in view of Kirkpatrick et al. (of the record), Campbell et al. (1998), Williamson et al. (1997), Goodman (US 6,022,910), Rath et al. (of the record), Tentolouris et al. (of the record), Kemper (1999) and Szapary et al. (2000).

Vester teaches nutritional supplement for cardiovascular health. Vester teaches that minerals and/or trace elements such as magnesium, zinc, selenium, copper and potassium; vitamins A, C, E, B₆ and B₁₂; niacin (niacinamide or nicotinic acid); folate (folic acid); beta-carotene; CoQ10, and a carrier can be components of the supplement (col. 3-5).

Vester does not teach transfer factor as a component of the nutritional supplement.

Kirkpatrick et al. teach a mammalian transfer factor specific for HSV (col. 4, lines 32-37) from colostrums extract.

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to combine the transfer factor specific for HSV of Kirkpatrick et al. with the nutritional supplement of Vester.

The skilled artisan would have been motivated to make such a modification because Campbell et al. teach that HSV along with other pathogens such as cytomegalovirus, *H. pylori*, or *C. pneumoniae* is associated with cardiovascular disease (p.573), and thus, a person of ordinary skill in the art would recognize that the transfer factor specific for HSV of Kirkpatrick et al. would have a benefit in treating or improving cardiovascular health.

In addition, it is well established that duplicating components with similar functions within a composition is obvious; see *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) and M.P.E.P. § 2144.04.

Furthermore, since it is well known in the art that transfer factor can be made specific to pathogens, it would have been obvious to a person of ordinary skill in the art to use transfer factors specific for cytomegalovirus, *H. pylori*, or *C. pneumoniae* as a cardiovascular support component as Campbell et al. teach that these pathogens are associated with cardiovascular diseases (Abstract and p.573).

Vester in view of Kirkpatrick et al. and Campbell et al. do not teach herbs such as Butcher's Broom, ginkgo biloba, hawthorn or garlic in the composition.

However, it is well known in the art that these herbs are beneficial to heart (cardiovascular system; circulatory system) according to Williamson et al. (Table at p.82-83). Williamson et al. teach that Butcher's Broom can be used for circulatory disorders; ginkgo biloba for stimulating circulation; hawthorn for lowering blood pressure and tonic to cardiovascular/circulatory system; and garlic for lowering blood pressure and reducing blood cholesterol.

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to combine the herbs of Williamson et al. with the nutritional supplement for cardiovascular health containing transfer factors specific for HSV or any other pathogens associated with cardiovascular diseases as taught by Vester in view of Kirkpatrick et al. and Campbell et al.

It is well established that duplicating components with similar functions within a composition is obvious; see *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) and M.P.E.P. § 2144.04.

Vester in view of Kirkpatrick et al., Campbell et al. and Williamson et al. do not teach resveratrol in the composition.

Goodman teaches resveratrol (also written as resrevatrol) for preventing cardiovascular disease (abstract).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to combine resveratrol of Goodman with the nutritional supplement of Vester in view of Kirkpatrick et al., Campbell et al. and Williamson et al.

With regard to the lysine or lysine salt (e.g. magnesium lysinate), Rath et al. teach lysine, which binds a LDL-receptor, for treatment of cardiovascular disease (abstract). Thus, a person of ordinary skill in the art would recognize the same purpose of treating and/or improving cardiovascular health from lysine or lysine salt as the nutritional supplement of Vester in view of Kirkpatrick et al., Campbell et al. Williamson et al. and Goodman. Rath et al. also teach nicotinic acid (niacin or its amide form as nicotinamide, niacinamide as family of vitamin B3) has the same benefit for

cardiovascular health (abstract).

With regard to the arginine or arginine salt (e.g. magnesium arginate), Tentolouris et al. teach that L-arginine administration improves the coronary blood flow suggesting that L-arginine may have benefit in patients with risk factors for atherosclerosis (abstract). It would have been obvious to a person of ordinary skill in the art to combine L-arginine or its well known salt form including arginate (e.g. magnesium arginate) of Tentolouris et al. with the nutritional supplement for cardiovascular health of Vester in view of Kirkpatrick et al., Campbell et al. Williamson et al. Goodman and Rath et al.

With regard to the limitation of ginger oil in claims 79 and 80, Kemper teaches that ginger (or ginger oil) is a cholesterol-lowering herb and has a potential clinical benefit in cardiovascular system (p. 1 and 4). It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to combine ginger oil as a herb beneficial for cardiovascular health with the nutritional supplement for cardiovascular health of Vester in view of Kirkpatrick et al., Campbell et al. Williamson et al. Goodman and Rath et al. with a reasonable expectation of success.

With regard to the limitation of red yeast rice extract in claims 79 and 80, Szapary et al. teach red yeast rice extracts for cardiovascular disease as lipid lowering agents (Table 1 and p.107). Szapary et al. also teach several ingredients discussed above such as antioxidants, CoQ10, Ginkgo biloba, folic acid, vitamin B6, B12, or L-arginine as helpful and/or beneficial agents for cardiovascular disease such as atherosclerosis (Table 1). It would therefore have been obvious for the person of ordinary skill in the art

at the time the invention was made to combine red yeast rice extract of Szapary et al. with the nutritional supplement for cardiovascular health of Vester in view of Kirkpatrick et al., Campbell et al. Williamson et al. Goodman and Rath et al. with a reasonable expectation of success.

M.P.E.P. §2144.06 states "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious).

With regard to the limitation of fat oxidation prevention element in claims 18 and 67, vitamin E taught by Vester is well known a fat oxidation prevention element.

With regard to the limitation drawn to the amount of transfer factor and vitamin C as in claim 72, it would have been obvious to a person of ordinary skill in the art to optimize the amount of the ingredient in the nutritional supplement of the references,

since the concentration of components is considered as a result-effective variable. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Claims 1, 4-6, 53-55 and 68-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vester (supra) in view of Kirkpatrick et al. (supra), Campbell et al. (supra), Williamson et al. (supra), Goodman (supra), Rath et al.(supra) and Tentolouris et al. (supra) in further view of Tokoro (of the record).

Vester in view of Kirkpatrick et al., Campbell et al. Williamson et al. Goodman, Rath et al. and Tentolouris et al. teach the limitations of claim 1 (see above).

Vester in view of Kirkpatrick et al., Campbell et al. Williamson et al. Goodman and Tentolouris et al. do not teach that the transfer factor is non-mammalian, avian or from egg extract.

Tokoro teaches transfer factor from egg extract of immunized hen (see Examples).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to replace the source of the transfer factor from

mammalian as of Kirkpatrick et al. to non-mammalian (e.g. avian) from egg extract as taught by Tokoro.

The skilled artisan would have been motivated to make such a modification because the production of transfer factor in a large amount from colostrums is difficult and limited due to its production is limited to a few days, and furthermore necessitates a vast farm land according to Tokoro (see column 1, lines 39-49).

The person of ordinary skill in the art would have had a reasonable expectation of success in producing transfer factor of Kirkpatrick et al. from eggs of immunized hen since it has been successfully practiced in the art.

With regard to the limitation drawn to the amount of transfer factor and vitamin C as in claim 70, it would have been obvious to a person of ordinary skill in the art to optimize the amount of the ingredient in the nutritional supplement of the references, since the concentration of components is considered as a result-effective variable.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 4:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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/Taeyoon Kim/
Examiner, Art Unit 1651